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| 10/801,307 | 03/16/2004 | Todd Robida | 03-183 | 1975 |

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| EXAMINER | |
|---|---|
| BOECKMANN, JASON J | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/801,307 | ROBIDA, TODD | |
| | Examiner | Art Unit | |
| | JASON J. BOECKMANN | 3752 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *3/10/2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 July 2009* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/5/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Drawings*

The drawings were received on 7/21/2009. These drawings are not acceptable. It appears that Detail L of figure 18a includes new matter. The drawings as originally filed did not show a fluid passage between the valve body 72 and the valve seat or valve diaphragm seal at all, especially not in the location now shown in Detail L of figure 8a. It is also noted that the original specification fails to specifically point out that there is a fluid passage between the valve body 72 and the valve seat or valve diaphragm, or that there is a fluid passage at all.

Additionally, figures 18b and 18c also appear to contain new matter. Nowhere in the originally figures was it shown that the valve diaphragm seal (84a of the new figure) or the air pressure diaphragm (78 of figure 11) flex or bend in such a manor as shown in figures 18b and 18c. It is also noted that nowhere in the original specification is specifically discussed that the valve diaphragm seal or the air pressure diaphragm are made out of a flexible material and flex when the valve changes valve positions. The valve could just as easily have operated with the valve diaphragm seal being rigid and movable inside the valve body.

It is noted that the drawing of record remain the originally filed drawings of 3/16/2004. The applicant is remained to amend the specification accordingly.

The drawings filed 3/16/2004 are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore,

the valve seats, diaphragms, plungers and all other internal parts of the valve, configured in the first position, second position and the default neutral position of the valve, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

In response to the applicant's arguments, the examiner is objecting to the drawings under rule 37 CFR 1.83(a), which clearly states that every feature of the invention specified in the claims must be shown in the drawings. The neutral position of

the valve is not shown in figure 11 nor does the specification indicate that figure 11 represents the neutral position of the valve. It is noted that the new figure 18a-18c clearly show how the valve operates, which elements move/flex, which elements do not move/flex, and how the fluid travels through the device. The only issue with the new figures is that there is no support for them in the disclosure as originally filled. One of ordinary skill in the art would not have necessarily known that that is the way the valve works without the applicant's extra explanations and the newly added figures. For example, one of ordinary skill in the art could just as easily have thought that elements 84a and 84b slide with plungers 77 and 94 instead of flexed when plungers 77 and 94 moved form the right to the left. Additionally one of ordinary skill in the art would not have necessarily known that the fluid passage was located between elements 86a and 72 as shown in new figure 18a, but could have easily though that the fluid passage was between elements 84a and 72 at the circumference of element 84a, or between elements 77 and 84a.

***Specification***

The amendment filed 7/21/2009 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The amendments to the specification relating to the newly added drawings appear to include new matter. See the drawing objections above.

Applicant is required to cancel the new matter in the reply to this Office Action.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Regarding claims 1, 2, 5, 6 and 11 it appears that there is no support in the originally filed disclosure for the term: “with no spring return mechanism.” The original specification disclose the prior art valve having a return spring mechanism (paragraph 32) and that in the valve of the present invention the return spring mechanism, or the prior art valve, is removed and replaced with a second pneumatic return. However, nowhere in the specification is it disclosed that the valve of the present invention does not have a spring return mechanism. Just because the spring return mechanism of the prior art valve is removed and replaced, doesn’t meant that there is not spring return mechanism. Additionally, the drawings do not appear to show a return spring mechanism, but it is noted that just because the drawings do not show a feature that doesn’t mean that that feature is not or never is present.

The examiner would also like to point out that the applicant argues that the elasticity of the flexible valve diaphragm seals is what causes the valve to return to its default neutral state (page 15, lines 4-7 of the applicant's arguments). The flexible valve diaphragm seals are therefore act as a spring return mechanisms and are therefore being considered return spring mechanisms.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7 and 11-20 are rejected, as best as understood, under 35 U.S.C. 103(a) as being unpatentable over the applicant's admitted prior art of figure 1 (everything but the valve 70), in view of Kintner (3,426,799).

The applicants admitted prior art discloses a medical device coating unit comprising a three-way valve (70), a solution reservoir (11) connected to a first port, a solution receptacle (14) connected to a second port, and a solution outlet (12) connected to a third port. The medical device being adapted to withdraw the coating solution form the reservoir (11) through the valve (70) and into the solution receptacle (14) and expel the coating material from the solution receptacle (14) through the valve

(70) and through the solution outlet (12). The admitted prior art does not specifically disclose that the valve is a pneumatically actuated three-way valve with no spring return mechanism and two valve seats.

However, Kintner shows a pneumatic actuated valve (figures 1 and 2) and a three-way valve (figure 3), both having no spring return mechanism. The three way valve comprising first (22), second (23) and third (24) valve ports, and the pneumatic actuated valves include two pneumatic ports (8 and 6), two air pressure diaphragms (the rubber seal on the top of elements 10 and 12), and two valve seats (any two of 13, 14 and 15).

It would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to combine the teachings of figures 1 and 2 of Kitner with the teaching of figure 3 in order provide a pneumatically actuated three-way valve, and substitute the new pneumatically actuated three-way valve of Kintner for the three-way valve of figure 1 in order to make the medical device operate more precisely by having a pneumatic return mechanism that can be adjusted.

Regarding claims 2 and 11, as well as understood, the three-way valve of Kintner comprises a position in which all valve seats remain open (see figure 3).

Regarding claims 3, 4, 12 and 13, the solution receptacle comprises a syringe (14) and the solution outlet comprises a spray nozzle (12).

Regarding claim 6, it is inherent that there is a supply pressure source in the device of the applicant's admitted prior art as modified by Kintner, however, one of ordinary skill in the art at the time of the applicant's invention would be able to supply a

pressure source, to the medical device of the admitted prior art as modified by Kintner, that provides a pressure within a range of about 300 kilo-Pascals to about 500 kilo-Pascals in order to move the valve form the first position to the second position more accurately.

Regarding claim 7, the medical device of the admitted prior art as modified by Kintner includes a first tube (13a) having a first diameter coupled to the first port (8) and a second tube (13c) having a second diameter coupled to the second port (6).

Regarding claim 10, the medical device of the admitted prior art as modified by Kintner includes one or more disposable fittings (16a, 16b, 16c, 16d of the admitted prior art).

Regarding claims 14-20, in its use, the device of the applicants admitted prior art, as modified by Kintner, will inherently perform the method steps of claims 14-20.

Claims 1-4, 6, 7 and 10-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liston (3,817,425) in view of Kintner (3,426,799).

Liston discloses a medical device coating unit comprising a three-way valve (300), a solution reservoir (272) connected to a first port (305), a solution receptacle (291) connected to a second port (307), and a solution outlet (226) connected to a third port (306). The medical device being adapted to withdraw the coating solution form the reservoir (272) through the valve (300) and into the solution receptacle (291) and expel the coating material from the solution receptacle (291) through the valve (300) and through the solution outlet (226). Liston does not specifically disclose that the valve is a

pneumatic actuated three-way valve with no spring return mechanism and two valve seats.

However, Kintner shows a pneumatic actuated valve (figures 1 and 2) and a three-way valve (figure 3), both having no spring return mechanism. The three way valve comprising first (22), second (23) and third (24) valve ports, and the pneumatic actuated valves include two pneumatic ports (8 and 6), two air pressure diaphragms (the rubber seal on the top of elements 10 and 12), and two valve seats (any two of 13, 14 and 15).

It would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to combine the teachings of figures 1 and 2 of Kitner with the teaching of figure 3 in order provide a pneumatically actuated three-way valve, and substitute the new pneumatic actuated three-way valve of Kintner for the three-way valve of Liston in order to make the medical device operate more precisely by having a pneumatic return mechanism that can be adjusted.

Regarding claims 2 and 11, the three-way valve of Kintner comprises a position in which all valve seats remain open (see figure 3).

Regarding claims 3, 4, 12 and 13, the solution receptacle comprises a syringe (291) and the solution outlet comprises a spray nozzle (226).

Regarding claim 6, it is inherent that there is a supply pressure source in the device of the Liston as modified by Kintner, however, one of ordinary skill in the art at the time of the applicant's invention would be able to supply a pressure source, to the medical device of the admitted prior art as modified by Kintner, that provides a pressure

within a range of about 300 kilo-Pascals to about 500 kilo-Pascals in order to move the valve form the first position to the second position more accurately.

Regarding claim 7, the medical device of Liston as modified by Kintner includes a first tube (275) having a first diameter coupled to the first port (305) and a second tube (298) having a second diameter coupled to the second port (307).

Regarding claims 14-20, in its use, the device of Liston, as modified by Kintner, will inherently perform the method steps of claims 14-20.

Claims 1-7 and 10-20 are rejected under 35 U.S.C. 103(a) as being unpatentable the applicant's admitted prior art of figure 1-8, in view of Kintner (3,426,799).

The applicants admitted prior art discloses a medical device coating unit comprising a three-way valve (20 the prior art valve with the spring return mechanism), a solution reservoir (11) connected to a first port, a solution receptacle (14) connected to a second port, and a solution outlet (12) connected to a third port. The medical device being adapted to withdraw the coating solution form the reservoir (11) through the valve (70) and into the solution receptacle (14) and expel the coating material from the solution receptacle (14) through the valve (70) and through the solution outlet (12), the three way valve comprising two valve seats and an air pressure diaphragm. The admitted prior art does not specifically disclose that the valve is a pneumatically actuated three-way valve comprising two air pressure diaphragms and with no spring return mechanism.

However, Kintner shows a pneumatic actuated valve that has a pneumatic port on one end, to move the valve assembly to the open position, and either a spring return mechanism (figures 4 and 5) or another pneumatic port on the other end (figure 4), to move the valve assembly to the closed position, therefore, Kintner teaches that an pneumatic port can be interchangeable with an return spring mechanism.

It would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to replace the spring return mechanism of the admitted prior art valve with a pneumatic port, including an air pressure diaphragm, in order to move the valve assembly in the opposite direction as the already existing pneumatic port and air pressure diaphragm, as taught by Kintner. This modification would give the valve more accuracy in positioning the valve assembly between the two valve seats.

Regarding claims 6 and 20, it is inherent that there is a supply pressure source in the device of the applicant's admitted prior art as modified by Kintner, however, one of ordinary skill in the art at the time of the applicant's invention would be able to supply a pressure source, to the medical device of the admitted prior art as modified by Kintner, that provides a pressure within a range of about 300 kilo-Pascals to about 500 kilo-Pascals in order to move the valve form the first position to the second position more accurately.

Regarding claims 2 and 11, as well as understood, the three-way valve of Kintner comprises a position in which all valve seats remain open (see figure 3).

Regarding claims 3, 4, 12 and 13, the solution receptacle comprises a syringe (14) and the solution outlet comprises a spray nozzle (12).

Regarding claim 6, each of the pneumatic ports inherently includes a supply pressure source that is capable of supplying a pressure within the claimed range.

Regarding claim 7, the medical device of the admitted prior art as modified by Kintner includes a first tube (13a) having a first diameter coupled to the first port (8) and a second tube (13c) having a second diameter coupled to the second port (6).

Regarding claim 10, the medical device of the admitted prior art as modified by Kintner includes one or more disposable fittings (16a, 16b, 16c, 16d of the admitted prior art).

Regarding claims 14-20, in its use, the device of the applicants admitted prior art, as modified by Kintner, will inherently perform the method steps of claims 14-20.

Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over the applicant's admitted prior art (figures 1-8), in view of Kintner (3,426,799) further in view of Chemline Plastics Ltd. (2001).

The applicant's admitted prior art as modified by Kintner shows all aspects of the applicant's invention as in claim 5, including threaded inserts (14, 15, 16), but does not specifically disclose that it contains stainless steel threaded inserts.

However, Chemline Plastics Ltd. shows a pneumatic valve with stainless steel threaded inserts (page 2).

It would have been obvious to on of ordinary skill in the art at the time of the applicant's invention to substitute the stainless steel threaded inserts of Chemline Ltd.

for the threaded inserts of the applicant's admitted prior, art as modified by Brown, in order to prevent corrosion.

Additionally, it is well known that stainless steel is an obvious choice of material for medical devices due to its ability to resist corrosion and be easily cleaned.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to make the valve body out of stainless steel in order to prevent corrosion.

In addition, It would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to make the valve body out of stainless steel along with the threaded inserts, since it has been held to be within the general skill of a worker in the art to select a know material on the basis of its suitability for the intended use as a matter of design choice (In re Leshin, 125 USPQ 416).

### ***Response to Arguments***

Applicant's arguments filed 3/10/2010 have been fully considered but they are not persuasive.

Since the applicant has not provided any new arguments, please see the examiner's previously presented arguments.

Regarding the applicants remarks concerning the 112 first paragraph rejections, it is noted that there is no enablement rejection, only a new matter rejection. Please see rejection above.

Regarding the applicants remarks towards the Kitner reference, Kitner discloses multiple embodiments including dual pneumatically actuated valves, three way valves and spring return valves. Kitner discloses a multiple valves with multiple means form operation, the rejection merely combines the three way valve of figure 3 with the means for operation shown in figures 1 and 2. The dual actuated valves comprising valve seats (any two of the three 13, 14 and 15) and air pressure diaphragms (the rubber elements on the outside of members 10 and 12). The air pressure diaphragms and valve seats of Kitner are air pressure diaphragms and valve seats to the same extent that the present invention has air pressure diaphragms and valve seats. Specifically, it appears form the figures that the air pressure diaphragm 78 is mounted on the piston 77 (or plunger) just as the air pressure diaphragm of Kitner is mounted on the piston 30 (or plunger). Additionally, figure 4 and 5 of Kitner are not being used to teach a three way valve as shown in figure 3, but are used to disclose that a dual actuated pneumatic valve is interchangeable with a single pneumatic/spring return valve, see the rejection above.

## *Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JASON J. BOECKMANN whose telephone number is (571)272-2708. The examiner can normally be reached on 8:00- 5:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Len Tran can be reached on (571) 272-1184. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. J. B./

Examiner, Art Unit 3752
4/6/2010
/Len Tran/
Supervisory Patent Examiner, Art Unit 3752